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| APPLICATION NO. 1                                                                                                      | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/538,882                                                                                                             | 06/14/2005  | Syunichirou Oshima   | 273243US0PCT                    | 8838                        |
| 22850 7590 06/04/2007<br>OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | EXAMINER<br>TONGUE, LAKIA J     |                             |
|                                                                                                                        |             |                      | ART UNIT<br>1645                | PAPER NUMBER                |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

Application No.

10/538,882

Applicant(s)

OSHIMA ET AL.

Examiner

Lakia J. Tongue

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2007 has been entered.

Claims 1-30 are pending and under examination. Claims 12 and 13 have been amended.

### ***Priority***

The certified translation of the priority document JP 2002-366769 is acknowledged. Consequently, Applicants claim to priority based on said document is deemed perfected and the date of December 18, 2002 will be used in determining the applicability of prior art.

### ***Rejections Withdrawn***

1. In view of Applicant's amendment the rejection of claims 12 and 13 under 35 U.S.C. 112, second paragraph as having insufficient antecedent basis for the limitation "wherein said *Flavobacterium psychrophilum* in a logarithmic growth phase are isolated from a growth culture by centrifugation or filtration" and "wherein said *Flavobacterium psychrophilum* in a logarithmic growth phase are inactivated" is withdrawn. The

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amendment of claims 12 and 13, to recite the limitation "wherein said components of inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase are isolated from a growth culture by centrifugation or filtration" and "wherein said inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase are inactivated", respectively obviates this rejection.

2. In view of Applicant's submission of the certified English translation of JP 2002-366769 the rejection of claims 1-30 under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kondo et al. (Diseases of Aquatic Organisms, August 4, 2003; 55(3): 261-64) is withdrawn.

3. In view of Applicant's arguments the rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Kondo et al. (Microbiol. Immunol., 2001; 45(12): 813-18) is withdrawn.

### ***Rejections Maintained***

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. The rejection of claims 1-9, 12-16, 20-22, 24, 26-28 and 30 under 35 U.S.C. 102(a) as being anticipated by LaFrentz et al. (Journal of Fish Disease, 2002; 25: 703-13) is maintained for the reasons set forth in the previous office action.

Applicant argues that:

1) There is no disclosure in LaFrentz et al. to show an increase in cell number during their growth conditions.

2) Based on the growth conditions reported in these references, Applicants submit that the culture would not be in logarithmic phase, but rather they would be in the stationary phase.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant. Subsequent claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of the composition according to claim 1 to a fish in need thereof to thus prevent cold-water disease.

With regard to Point 1, logarithmic phase is defined as the phase where binary fission occurs and the rate of increase in cell number is multiplication function of cell number. The culture conditions of LaFrentz et al. are such that the cells would be in logarithmic phase. LaFrentz et al. evidence this where it is disclosed that *F. psychrophilum* cultures were grown in 2 L volumes for 72 hours (see pages 704-705). In absence of evidence to the contrary the cultures would be in logarithmic phase.

With regard to Point 2, Applicant's assertions comprise only attorney's argument; said argument cannot be considered evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145.

As previously presented, LaFrentz et al. disclose a vaccine that comprises killed *Flavobacterium psychrophilum* cells, which were effective against bacterial coldwater disease in fish (page 705 & 710; 1<sup>st</sup> column). LaFrentz et al. disclose that *Flavobacterium psychrophilum* cells were killed by formalin and harvested by centrifugation. Moreover, LaFrentz disclose that the cells were re-suspended in physiological saline (page 705, 1<sup>st</sup> column, 1<sup>st</sup> paragraph). Inherently, the inactivated cells components comprise cell membrane components, vesicles, and/or secretory products.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. the ability to prevent cold water disease in

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fish. The purification, isolation or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process (i.e. isolation via centrifugation, filtration, or ultrasonic pulverization) does not change properties of the product in an unexpected manner. See In re Thorpe, 227 USPTO 964 (CAFC 1985); In re Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPTO 685 (CCPA 1972).

Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Moreover, LaFrentz et al. disclose a method for preventing cold-water disease in rainbow trout by administering a vaccine comprising killed *Flavobacterium psychrophilum* cells (pages 704- bacterial culture; 705-fish immunizations).

Additionally, LaFrentz disclose that the fish were immunized by immersion. Bath solutions were prepared by suspending formalin-killed *Flavobacterium psychrophilum* cells in water. For rainbow trout immunizations, an additional immersion was included (page 705, immersion delivery). The method of the prior art is the same of that which is claimed. Limitations such as an effective dosage range and when to collect inactivated cells are being viewed as limitations of optimizing experimental parameters.

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5. The rejection of claims 1-8, 12-15, 20-22, 24, 26-28 and 30 under 35 U.S.C. 102(b) as being anticipated by Masunari et al. (Bulletin of the Fisheries Experiment Station, Okayama Prefecture, 2001; 16: 49-57 (translation pages 1-14)) is maintained for the reasons set forth in the previous office action.

Applicant argues that:

1) There is no disclosure in Masunari et al. to show an increase in cell number during their growth conditions.

2) Based on the growth conditions reported in these references, Applicants submit that the culture would not be in logarithmic phase, but rather they would be in the stationary phase.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant. Subsequent claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of the composition according to claim 1 to a fish in need thereof to thus prevent cold-water disease.

With regard to Point 1, logarithmic phase is defined as the phase where binary fission occurs and the rate of increase in cell number is multiplication function of cell number. The culture conditions of Masunari et al. are such that the cells would be in logarithmic phase. Masunari et al. disclose a logarithmic grow phase in the growth

curve in Fig 1 as well as the results (see page 814). In absence of evidence to the contrary the cultures would be in logarithmic phase.

With regard to Point 2, Applicant's assertions comprise only attorney's argument; said argument cannot be considered evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art. Additionally, the arguments of counsel cannot take the place of evidence in the record. In *re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In *re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration MPEP 2145.

As previous presented Masunari et al. disclose a vaccine comprising formalin-killed *Flavobacterium psychrophilum* cells. Moreover, Masunari et al. disclose that the vaccine is to be used for the prevention of the cold-water disease in Ayu (fish) (see page 4, paragraph 3; title). The vaccine of the prior art is the same of that which is claimed. Inherently, the inactivated cells components comprise cell membrane components, vesicles, and/or secretory products.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. the ability to prevent cold water disease in

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fish. The purification, isolation or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process (i.e. isolation via centrifugation, filtration, or ultrasonic pulverization) does not change properties of the product in an unexpected manner. See In re Thorpe, 227 USPTO 964 (CAFC 1985); In re Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPTO 685 (CCPA 1972).

Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Moreover, Masunari et al. disclose a method for preventing the cold-water disease in fish, comprising administering 0.05 ml of inactivated cells of *Flavobacterium psychrophilum* to fish (see page 4, paragraph 4). The method of the prior art is the same of that which is claimed. Limitations such as an effective dosage range and when to collect inactivated cells are being viewed as limitations of optimizing experimental parameters.

6. The rejection of claims 1-8, 12-15, 20-22, 24, 26-28 and 30 under 35 U.S.C. 102(b) as being anticipated by Rahman et al. (Fish and Shellfish Immunology, 2002; 12: 169-79) is maintained for the reasons set forth in the previous office action.

Applicant argues that:

- 1) Rahman et al. does not disclose or suggest an inactivated vaccine.
- 2) Rahman et al. does not suggest any relationship between the virulence and the vaccine's efficacy, much less disclose that there is a higher effect of the vaccine which is made from a logarithmic phase culture.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant. Subsequent claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of the composition according to claim 1 to a fish in need thereof to thus prevent cold-water disease.

With regard to Point 1, Rahman et al. disclose that cultures were grown and harvested by centrifugation while still in logarithmic growth phase (see page 173; culture conditions in broth medium). Further, Rahman et al. disclose that formalin killed bacteria was used for the vaccine in question (see page 170).

With regard to Point 2, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the relationship between the virulence and the vaccine's

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efficacy) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, the claimed product is the same as the product, which has been disclosed in the prior art and would necessarily have the same immunological properties.

As previously presented, Rahman et al. disclose a *Flavobacterium psychrophilum* vaccine based on the antigenic outer membrane fraction of the cell (abstract). Rahman et al. disclose that the bacterin was inactivated with formalin (see page 170, preparation of the vaccines). Lastly, Rahman et al. disclose that the supernatant was centrifuged and re-suspended in distilled water (see page 171, 1<sup>st</sup> full paragraph). The vaccine of the prior art is the same of that which is claimed.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. the ability to prevent cold water disease in fish. The purification, isolation or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process (i.e. isolation via centrifugation, filtration, or ultrasonic pulverization) does not change properties of the product in an unexpected manner. See *In re Thorpe*, 227 USPTO 964 (CAFC 1985); *In re Marosi*, 218 USPTO 289, 29222-293 (CAFC 1983); *In re Brown*, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or

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property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Moreover, Rahman et al. disclose a method for preventing cold-water disease in rainbow trout and ayu (abstract). Moreover, Rahman et al. disclose that the fish were immunized with a *Flavobacterium psychrophilum* vaccine based on the antigenic outer membrane fraction (see abstract and page 171-vaccination). The method of the prior art is the same of that which is claimed. Limitations such as an effective dosage range and when to collect inactivated cells are being viewed as limitations of optimizing experimental parameters.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 12, and 13 are rendered vague and indefinite by the use of the term

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"inactivated". It is unclear what is meant by said term, as it is not explicitly defined in the specification. What constitutes "inactivated"? If the cells are not alive they cannot be in a log phase. What core features/structures must be maintained? As written, it is impossible to determine the metes and bounds of the claimed invention.

8. Claim 14 recites the limitation "wherein said *Flavobacterium psychrophilum* in a logarithmic growth phase are inactivated by formalin treatment". However, claim 2 is drawn to components of inactivated cells of *Flavobacterium psychrophilum*. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3, 4, and 19-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of a pharmaceutical composition comprising components of inactivated cells of *Flavobacterium psychrophilum* in a

logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretary products to a fish in need thereof to thus prevent cold-water disease.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must demonstrate the ability to prevent cold-water disease in fish, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus.

Moreover, the skilled artisan cannot envision administering an effective dosage of a pharmaceutical composition comprising components of a whole organism or inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretary products to a fish in need to prevent cold-water disease. The claims encompass a genus, which is not adequately described. Lastly, the instant claims are drawn to a method for the prevention of cold-water disease, however no protective (prevention) measures have

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been disclosed with inactivated whole cells, cell membrane components, vesicles, or secretory products of *Flavobacterium psychrophilum*. The specification is silent with regard to which component(s) will convey the protective response as claimed.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential ability to bind a specific biological agent. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

*The University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404. 1405 held that: "...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re *Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an Applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention" (Id. at 1104). Moreover, an adequate written description of the claimed invention must include sufficient

description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the Applicant had possession of the claimed invention at the time the instant application was filed.

10. Claims 3, 4, and 19-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

*In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as

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originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors have been considered in the establishment of this scope of enablement rejection. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

***Nature of the invention:*** The instant claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of a pharmaceutical composition comprising components of inactivated cells of

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*Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretary products to a fish in need thereof to thus prevent cold-water disease.

**Breadth of the claims:** The claims are broadly drawn and encompass administering an effective dosage of a pharmaceutical composition comprising components of inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and/or cell membrane components, vesicles, and/or secretary products and at least one pharmaceutically acceptable carrier or adjuvant to a fish in need thereof to prevent cold-water disease. Moreover, the instant claims encompass administering an indistinguishable and undetermined number of cell membrane components, vesicles, and/or secretary products to prevent cold-water disease. Lastly, the instant claims are drawn to a method for the prevention of cold-water disease, however no protective (prevention) measures have been disclosed.

**Direction or guidance presented in the specification:** To be a prophylactic method, said method must induce a protective immune response demonstrated by challenge experiments in an acceptable model. The specification does not provide substantive evidence that the claimed method is capable of inducing protective immunity against cold-water disease when administered a whole organism or inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretary products. The

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specification is equally silent with regard to which organism or cell components provide efficacy for the claimed method. Moreover, the components that convey the protective response have not been described. This demonstration is required for the skilled artisan to be able to use the claimed method for their intended purpose of preventing cold-water disease in fish. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed composition, i.e. would not be able to accurately predict if protective immunity has been induced. The specification does not provide a demonstration where a pathogen free subject was administered the claimed composition and as a result the subject was protected from cold-water disease. There is insufficient direction or guidance presented in the specification with regard to the prevention of cold-water disease in a subject when said composition is administered.

Moreover, the specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. The specification does not demonstrate a method for preventing cold-water disease in fish, comprising administering an effective dosage of a pharmaceutical composition comprising a whole organism or components of inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretory products to a fish in need thereof to thus prevent cold-water disease. The specification generally discloses that administration of *Flavobacterium psychrophilum* G3724 increases the survival rate, but it does not

contemplate administering said composition to demonstrate its efficacy against cold-water disease. Again, the specification does not provide a demonstration where a pathogen free subject or otherwise was administered inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretary products and as a result the subjects disease was ameliorated or prevented. Increasing the subjects survival rater does not necessarily indicate that inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at lest one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretary products prevented the cold-water disease.

**Presence or absence of working examples:** There are no working examples, which suggest a method of preventing cold-water disease in fish when a fish is administered inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at lest one pharmaceutically acceptable carrier or adjuvant, wherein said components comprises cell membrane components, vesicles, and/or secretary products.

**State of the prior art:** Ryce et al. (Bacterial Coldwater Disease in Westslope Cutthroat Trout: Hatchery Epidemiology and Control, Montana Cooperative Fishery Research Unit; June 2004; pages 1-13) disclose that at present, the most effective form of disease control is to prevent outbreaks from occurring by reducing stress on the fish (see page 4, 1<sup>st</sup> paragraph).

***Quantity of experimentation necessary:*** The quantity of experimentation necessary would be undue as no relevant evidence has been made of record establishing the amount of experimentation necessary. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the claimed genus. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidence by the state of the prior art, attempting the construct and test variants of the claimed invention would constitute undue experimentation.

### ***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT  
5/22/07



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